REMARKS

Applicants have amended claims 1, 3, 4, 7, 8, 10, 13, and 14 to promote clarity, correct grammatical errors, and conform the claims to proper formality. No new matter has been introduced by the amendment.

Claims 1-14 are currently pending. Reconsideration of this application, as amended, is respectfully requested in view of the remarks below.

Rejection under 35 U.S.C. § 112, first paragraph

Claim 13, drawn to a DNA vaccine containing an antigenic gene, stands rejected for lack of enablement. The Examiner asserted that this claim encompasses DNA vaccines containing any and all antigenic genes, the majority of which would be inoperative, and, therefore, undue experimentation would be required to practice the claimed invention. See the Office Action, page 3, line 1 through page 4, line 8.

Applicants respectfully traverse. According to MPEP 2164.01, the test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue; and the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. It is also well established that "[a] considerable amount of experimentation is permissible, if it is merely routine (emphasis added)." See, *In re Wands*, 8 USPQ2d 1400, 1404 (CAFC 1988). As pointed out by Applicants in their response to the office action dated August 24, 2002, methods of determining the efficacy of a vaccine are well known and routinely practiced in the art (see page 6, lines 5-14). Whether a Lac shuttle vector carrying an antigenic gene would be effective in inducing a protective immune response can be determined using these methods as routinely practiced by a skilled artisan. Thus, the experimentation required to practice the claimed invention is not undue. Even if such experimentation may be complex and in a considerable amount, it is permissible. In sum, since no undue experimentation is needed, claim 13 is enabled.

NEW GROUNDS FOR REJECTION

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 1-6, 10, and 12-14 for lack of written description on two grounds. More specifically, the Examiner asserted that a single example (i.e., the repA gene or the β-galactosidase gene) does not provide sufficient description for claims encompassing a genus (i.e., a gene encoding a protein involved in the replication of a lactic acid bacterial plasmid or a non-antibiotic resistance marker gene). See the Office Action, page 4, line 10 through page 7, line 5.

Applicants respectfully traverse. Claim 1, drawn to a Lac shuttle vector containing (1) a gene encoding a protein involved in the replication of a lactic acid bacterial plasmid and (2) a non-antibiotic resistance marker gene, will be discussed first.

To satisfy the written description requirement, the specification, when read in light of the knowledge possessed by those skilled in the art (*In re Lange*, 644 F.2d 863, 209 USPQ 294, CCPA 1981), conveys that Applicants were in possession of the claimed invention at the time the application was filed. Several proteins (e.g., copA, repA, and replication proteins) have been shown to be involved in the replication of a lactic acid bacterial plasmid. At the time the application was filed, genes encoding these proteins were known in the art, and had been used for plasmid construction. See, e.g., Cocconcelli et al. (1996) Res. Microbiol. 147(8):619-624, a copy of which is attached hereto as "Exhibit A;" Kanatani et al. (1995) 133(1-2):127-30, a copy of which is attached hereto as "Exhibit B;" Klein et al. (1993) Plasmid (1):14-29, a copy of which is attached hereto as "Exhibit C;" and Imanaka et al. (1986) Mol. Gen. Genet. 205(1):90-6, a copy of which is attached hereto as "Exhibit D." Also, at the time the application was filed, non-antibiotic resistance marker genes (e.g., supD, lacF, and lacZ) were known in the art, and had been routinely used in the selection of plasmid constructs. See, e.g., Sorensen et al. (2000) Applied and Environmental Microbiology 66:1253-1258, a copy of which is attached hereto as "Exhibit E;" de Vos (1999) International Dairy Journal 9:3-10, a copy of which is attached hereto as "Exhibit F;" and Platteeuw et al. (1996) Applied and Environmental Microbiology 62:1008-1031, a copy of which is attached hereto as "Exhibit G."

As correctly pointed out by the Examiner, Applicants have demonstrated that one of the genes encoding proteins involved in the replication of a lactic acid bacterial plasmid (i.e., the repA gene) and one of the non-antibiotic resistance marker genes (i.e., the lacZ gene encoding β-galactosidase) can be used in the Lac shuttle vector of claim 1. Other genes encoding proteins involved in the replication of a lactic acid bacterial plasmid and other genes encoding non-antibiotic resistance markers can also be used in the Lac shuttle vector of claim 1 following the examples of repA and lacZ, respectively. Given the level of knowledge and skill in the art and the examples provided in the specification, a skilled artisan would have been conveyed that Applicants, at the time the application was filed, had possession of the claimed invention.

In this connection, Applicants would like to bring to the Examiner's attention that Applicants are **not** required to disclose every species encompassed by their claims. See, e.g., *In re Angstadt*, 190 USPQ 214, 218 (CCPA 1976). Unreasonable limitation of Applicants' claims to the tested species (i.e., the repA and β-galactosidase genes) would lead to a grossly unjust result: other persons of ordinary skill in the art can easily avoid Applicants' claims, while following the direction and guidance articulated by Applicants in the specification, by conveniently selecting and using any untested species (e.g., a gene encoding another replication protein or any other non-antibiotic resistance marker gene such as supD or lacF), without undue experimentation.

For the reasons set forth above, Applicants submit that claim 1 meets the written description requirement. By the same token, claims 1-6 and 10 (dependent from claim 1) and claims 12-14 (referring to claim 1) also meet the written description requirement.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner further rejected claims 1, 7, 8, 10, and 11 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. See the Office Action, page 7, line 6 through page 8, line 3.

Specifically, the Examiner requested clarification of the term "thereof" recited in claim 1. Applicants have amended the claim in accordance with the Examiner's suggestion. The Examiner also requested clarification of the term "a degenerative variant thereof" recited in

claims 7 and 8. Applicants have replaced this term with "a variant thereof that contains degenerative protein-coding sequences." Finally, the Examiner pointed out that the term "host cell" recited in claims 10 and 11 lacks antecedent basis. Applicants have corrected this error by amending claim 10 as shown above.

Objection

The Examiner objected to claim 9 as being dependent from rejected claim 1. As mentioned above, the grounds for rejections of claim 1 have been overcome. The objection to claim 9 should be withdrawn.

CONCLUSION

Applicants submit that the grounds for rejection and objection asserted by the Examiner have been overcome, and that claims 1-14, as pending, define subject matter that is fully enabled, sufficiently described, and definite. On this basis, it is submitted that allowance of this application is proper, and early favorable action is solicited.